SH-48

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409 Third Street, SW
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Subject: Rulemaking number RIN 3245-AF22
Re: "SBIR Size Standards for Venture Capital Companies"

We are a small biotechnology company that has participated in the SBIR program in the past and we are responding to the SBA's request for comments.

We feel that many small biotechnology companies are being shut out of the SBIR program due to the reinterpretation of the SBIR eligibility rule requiring 51% ownership by U.S. *individuals* which is now being interpreted by the SBA as "natural persons." This interpretation of *individuals* excludes venture capital firms and thus excludes many otherwise eligible small private biotechnology companies from accepting SBIR grant funds.

It seems inconsistent with the nature of the SBIR program that an eligibility requirement disqualifies the majority of biotechnology companies from obtaining SBIR funds based on one of the most common funding sources used to start up such companies. Biotechnology is a unique industry with an atypical small company life cycle. In order to even start operations, significant cash outlays need to be made to build infrastructure and purchase the expensive specialized scientific equipment needed to perform our innovative work. This cash usually comes from at least several venture capital firms that invest money in fledgling companies with no near term profit in sight. Because startup biotechnology companies take years to develop a profit and can often take decades before reaching profitability, it is generally venture capital funds and not individual people who can afford to invest in such companies.

Incorporated in 1998, our company with ~110 employees is typical of startup biotechnology companies that have venture capital backing. We are working on the discovery of new therapies that address important diseases. Without venture capital support, we would have been unable to initiate and maintain operations. We have a number of research projects at various stages of discovery and development. Earlier stage projects employing novel approaches are often considered more speculative and therefore less attractive by venture capital firms, and it is for these projects that we have applied to the National Institutes of Health (NIH) for SBIR grants in the past. The cutting edge nature of our research has been evidenced by the consistently high ratings our applications have received and by our publications in prestigious peer reviewed journals such as *Science* and *Proceedings of the National Academy of Science.* Since we have been restricted from accessing SBIR funds, we have been forced to terminate our early stage innovative projects. Please note that the SBA asked for comments about whether allowing small biotechnology companies that are majority owned by venture capital firms to partake in the SBIR program might "shift the program toward lower-risk technologies that are closer to the market." Actually, in our case the reverse is true.

If venture capital backed companies continue to be eliminated from the SBIR applicant pool, a highly productive category of companies will be excluded from this important funding source. This will directly harm the U.S. public since it is through small biotechnology company innovation that truly novel drugs to treat human disease are often discovered. Since the mission of the SBIR program at the NIH is to advance the health of the U.S. public, a policy rule that excludes the most promising small companies with the most innovative programs simply does not make sense.

Consequently, we believe that language defining a "Small Business Entity" should be changed to include those small biotechnology businesses that are majority owned by venture capital backed companies.

We are sending this letter anonymously since we have been advised to do so.

Thank you